

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF UTAH**

LINDA P. SMITH,

Plaintiff,

v.

XAVIER BECERRA, in his official  
capacity as Secretary of Health and  
Human Services,

Defendant.

Case No. 1:21-cv-47-HCN-DBP

**AMENDED ANSWER**

Pursuant to Federal Rule of Civil Procedure 15(a)(1)(A), the Defendant, Xavier Becerra, Secretary of Health and Human Services (the “Secretary”), respectfully amends his answers to the allegations of the Complaint as follows. The Secretary notes that, pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court’s review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings.

1. This paragraph consists of plaintiff’s characterization of this lawsuit, to which no response is required.

2. This paragraph consists of plaintiff’s legal conclusions regarding subject-matter jurisdiction, to which no response is required.

3. This paragraph consists of plaintiff’s legal conclusions regarding venue, to which no response is required.

4. Admitted that Mrs. Smith in an individual and is eligible for Medicare. The Secretary lacks sufficient knowledge or information to form a belief about the truth of the allegation that Mrs. Smith is currently a resident of Utah.

5. Admitted that Xavier Becerra is the Secretary of Health and Human Services. The remainder of this paragraph consists of plaintiff's characterization of this lawsuit, to which no response is required.

6. This paragraph consists of factual allegations regarding diabetes. The final two sentences describe a report published by the Centers for Disease Control, which speaks for itself. The Secretary lacks sufficient knowledge or information to form a belief about the truth of the remainder of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these factual allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case.

7. This paragraph consists of factual allegations regarding diabetes. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these factual allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case.

8. This paragraph consists of factual allegations regarding diabetes. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate

statement of its contents. To the extent that these factual allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case.

9. This paragraph consists of factual allegations regarding diabetes. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these factual allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case.

10. This paragraph consists of factual allegations regarding diabetes. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these factual allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case.

11. This paragraph consists of factual allegations regarding diabetes. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these factual allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case.

12. This paragraph consists of factual allegations regarding glucose tests. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these factual allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case.

13. This paragraph consists of factual allegations regarding glucose tests. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these factual allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case.

14. This paragraph consists of factual allegations regarding continuous glucose monitors. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these factual allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case.

15. This paragraph consists of factual allegations regarding continuous glucose monitors. The Secretary lacks sufficient knowledge or information to form a belief about the truth

of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these factual allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case.

16. This paragraph consists of factual allegations regarding continuous glucose monitors. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these factual allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case.

17. This paragraph consists of factual allegations regarding continuous glucose monitors. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these factual allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case.

18. This paragraph consists of factual allegations regarding continuous glucose monitors. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their

respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these factual allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case.

19. This paragraph consists of factual allegations regarding continuous glucose monitors. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these factual allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case.

20. This paragraph consists of factual allegations regarding continuous glucose monitors. The fourth sentence describes a report published by the Centers for Disease Control, which speaks for itself. The Secretary lacks sufficient knowledge or information to form a belief about the truth of the remaining allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these factual allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case.

21. This paragraph consists of factual allegations regarding continuous glucose monitors. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their

respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these factual allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case.

22. This paragraph consists of factual allegations regarding continuous glucose monitors. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these factual allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case.

23. This paragraph consists of factual allegations regarding continuous glucose monitors. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these factual allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case.

24. Admitted that the Food and Drug Administration (FDA) has approved the Dexcom G5 Mobile Continuous Glucose Monitoring System for commercial distribution. This paragraph summarizes and characterizes the FDA's premarket approval decision, which speaks for itself.

25. Admitted that the Secretary has adhered to the view that some continuous glucose monitors are not covered as durable medical equipment. Denied that the Secretary has "resisted" covering such devices, or that his position has been "[i]nexplicabl[e]."

26. This paragraph consists of plaintiff's characterizations of the Medicare statute, to which no response is required. The Court is respectfully referred to the cited statutory provisions for a full and complete statement of their contents.

27. This paragraph consists of plaintiff's characterizations of the Secretary's regulations, to which no response is required. The Court is respectfully referred to the cited regulatory provision for a full and complete statement of its contents.

28. This paragraph consists of plaintiff's characterization of the Medicare statute, to which no response is required. Admitted that the statute contains the quoted language. The Court is respectfully referred to the cited statutory provision for a full and complete statement of its contents.

29. This paragraph consists of plaintiff's characterization of the Medicare statute, to which no response is required. The Court is respectfully referred to the cited statutory provisions for a full and complete statement of their contents.

30. Admitted that CMS Ruling 1682-R was issued on January 12, 2017, and was not preceded by notice and an opportunity for public comment. Denied that the phrase "final opinion and order" appears in CMS Ruling 1682-R. Plaintiff's characterizations of CMS Ruling 1682-R are denied. The Court is respectfully referred to the cited CMS Ruling for a full and complete statement of its contents.

31. Admitted that the phrase "binding on all CMS components, on all Department of Health and Human Services components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration" appears in CMS Ruling 1682-R, at page 1. Plaintiff's characterizations of CMS Ruling 1682-R are denied. The Court is respectfully referred to the cited CMS Ruling for a full and complete statement of its contents.



32. Plaintiff's characterizations of CMS Ruling 1682-R are denied. The Court is respectfully referred to the cited CMS Ruling for a full and complete statement of its contents.

33. Plaintiff's characterizations of CMS Ruling 1682-R are denied. The Court is respectfully referred to the cited CMS Ruling for a full and complete statement of its contents. Admitted that CMS Ruling 1682-R contains the quoted language. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these factual allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case.

34. Plaintiff's characterizations of CMS Ruling 1682-R are denied. The Court is respectfully referred to the cited CMS Ruling for a full and complete statement of its contents.

35. Admitted that the Secretary has denied Medicare coverage for some continuous glucose monitors on the grounds that they are not "primarily and customarily used to serve a medical purpose" within the meaning of the Medicare regulations. The Secretary otherwise lacks sufficient knowledge or information to form a belief about the truth of these factual allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these factual allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case.

36. Denied.

37. Admitted that Local Coverage Determination L33822 and Policy Article A52464 were revised to account for CMS Ruling 1682-R, and that this revision was not preceded by notice and an opportunity to comment. The Court is respectfully referred to Local Coverage Determination L33822 and Policy Article A52464 for a full and complete statement of their contents.

38. Denied.

39. Admitted that the Secretary has denied coverage of certain continuous glucose monitors on the grounds that they are not “primarily and customarily used to serve a medical purpose” within the meaning of the Medicare Part B regulations.

40. Admitted that the Secretary has adhered to the view that some continuous glucose monitors are not covered as durable medical equipment. The characterizations of Policy Article A52464 are denied. The Court is respectfully referred to Policy Article A52464 for a full and complete statement of its contents. Otherwise denied.

41. Admitted that Medicare coverage of continuous glucose monitors has been reviewed by several district courts.

42. Admitted that some administrative law judges have concluded that certain continuous glucose monitors are covered as durable medical equipment under the Medicare statute and regulations. The Secretary otherwise lacks sufficient knowledge or information to form a belief about the truth of these factual allegations. The web address provided in this paragraph appears to be inactive.

43. Admitted that certain district courts have concluded that continuous glucose monitors are covered as durable medical equipment under the Medicare Part B statute and regulations.

44. The Secretary denies the characterizations of the cited district court decisions, which speak for themselves. The Court is respectfully referred to the cited decisions for a full and complete statement of their contents.

45. The Secretary denies the characterizations of the district court decisions described in this paragraph, which speak for themselves. The Court is respectfully referred to those district court decisions for a full and complete statement of their contents.

46. The Secretary denies the characterization of the cited administrative decision, which speaks for itself. The Court is respectfully referred to the cited decision for a full and complete statement of its contents.

47. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case, and no response is required.

48. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case, and no response is required.

49. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case, and no response is required.

50. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case, and no response is required.

51. Admitted that Mrs. Smith was prescribed a MiniMed 630G system, which is an insulin pump. Admitted that Mrs. Smith was also prescribed with sensors and a transmitter for a continuous glucose monitoring system.

52. Admitted that the sensors and transmitter communicate with the insulin pump. Otherwise denied.

53. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for

a full and accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case, and no response is required.

54. This paragraph consists of plaintiff's legal conclusions and characterizations of the proceedings in ALJ Appeal Nos. 1-6020086584 and 1-6020086584R1. No response to the legal conclusions is required, and the characterizations are denied. It is specifically denied that, in ALJ Appeal Nos. 1-6020086584 & 1-6020086584R1, "Mrs. Smith . . . litigated the issue[] of whether her CGM"—that is, the device she was provided on December 13, 2016, the coverage of which is at issue here—was covered by Medicare Part B. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case, and no response is required.

55. Admitted that the decision in ALJ Appeal No. 1-6020086584R1 indicates that Mrs. Smith received continuous glucose monitor sensors on October 29, 2015. The Secretary otherwise lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case, and no response is required.

56. Admitted.

57. Admitted that Administrative Law Judge Lambert held a hearing in ALJ Appeal No. 1-6020086584. The Secretary otherwise lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case, and no response is required.

58. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case, and no response is required.

59. It is denied that, in ALJ Appeal No. 1-6020086584, "The issue[] of whether Mrs. Smith's CGM"—that is, the device she was provided on December 13, 2016, the coverage of which is at issue here—was covered by Medicare Part B "was actually litigated before ALJ Lambert." The Secretary otherwise lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these allegations are not

reflected in the administrative record, they are beyond the scope of the Court's review in this case, and no response is required.

60. Admitted that Administrative Law Judge Lambert issued a decision in ALJ Appeal No. 1-6020086584 on May 1, 2017, and found that the supplies in question were covered by Medicare Part B.

61. This paragraph consists of plaintiff's legal conclusions and characterizations of the proceedings in ALJ Appeal No. 1-6020086584. No response to the legal conclusions is required, and the characterizations are denied. It is specifically denied that, in ALJ Appeal No. 1-6020086584, "ALJ Lambert found that Mrs. Smith's CGM"—that is, the device she was provided on December 13, 2016, the coverage of which is at issue here—was "covered by Medicare." Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case, and no response is required.

62. This paragraph consists of plaintiff's legal conclusions and characterizations of the proceedings in ALJ Appeal No. 1-6020086584. No response to the legal conclusions is required, and the characterizations are denied. It is specifically denied that, in ALJ Appeal No. 1-6020086584, "ALJ Lambert determin[ed] that Mrs. Smith's CGM"—that is, the device she was provided on December 13, 2016, the coverage of which is at issue here—was "covered by Medicare." Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and

accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case, and no response is required.

63. Admitted that the Medicare Appeals Council reversed the decision in ALJ Appeal No. 1-602008658464 and remanded for further proceedings. This paragraph consists of plaintiff's legal conclusions and characterizations of the proceedings before the Medicare Appeals Council. No response to the legal conclusions is required, and the characterizations are denied. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case, and no response is required.

64. Admitted that Administrative Law Judge Lambert held a hearing in ALJ Appeal No. 1-6020086584R1 on April 4, 2018. The Secretary otherwise lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case, and no response is required.

65. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their



respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case, and no response is required.

66. This paragraph consists of plaintiff's legal conclusions and characterizations of the proceedings in ALJ Appeal No. 1-6020086584R1. No response to the legal conclusions is required, and the characterizations are denied. It is specifically denied that, in ALJ Appeal No. 1-6020086584R1, "The issue[] of whether Mrs. Smith's CGM"—that is, the device she was provided on December 13, 2016, the coverage of which is at issue here—was covered by Medicare Part B "was actually litigated before ALJ Lambert." Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case, and no response is required.

67. Admitted that Administrative Law Judge Lambert issued a decision in ALJ Appeal No. 1-6020086584R1 on April 24, 2018, and found that the supplies in question were covered by Medicare Part B.

68. This paragraph consists of plaintiff's legal conclusions and characterizations of the proceedings in ALJ Appeal No. 1-6020086584R1. No response to the legal conclusions is required, and the characterizations are denied. It is specifically denied that, in ALJ Appeal No. 1-6020086584R1, "ALJ Lambert found that Mrs. Smith's CGM"—that is, the device she was provided on December 13, 2016, the coverage of which is at issue here—was "primarily and

customarily used to serve a medical purpose.” Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court’s review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court’s review in this case, and no response is required.

69. This paragraph consists of plaintiff’s legal conclusions and characterizations of the proceedings in ALJ Appeal No. 1-6020086584R1. No response to the legal conclusions is required, and the characterizations are denied. It is specifically denied that, in ALJ Appeal No. 1-6020086584R1, “ALJ Lambert . . . found that Mrs. Smith’s CGM”—that is, the device she was provided on December 13, 2016, the coverage of which is at issue here—was “durable medical equipment.” Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court’s review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court’s review in this case, and no response is required.

70. This paragraph consists of plaintiff’s legal conclusions and characterizations of the proceedings in ALJ Appeal No. 1-6020086584R1. No response to the legal conclusions is required, and the characterizations are denied. It is specifically denied that, in ALJ Appeal No. 1-6020086584R1, “ALJ Lambert . . . found that Mrs. Smith’s CGM”—that is, the device she was provided on December 13, 2016, the coverage of which is at issue here—was “medically reasonable and necessary.” Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court’s review in this

action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court’s review in this case, and no response is required.

71. This paragraph consists of plaintiff’s legal conclusions and characterizations of the proceedings in ALJ Appeal No. 1-6020086584R1. No response to the legal conclusions is required, and the characterizations are denied. It is specifically denied that, in ALJ Appeal No. 1-6020086584R1, “ALJ Lambert . . . found that Mrs. Smith’s CGM”—that is, the device she was provided on December 13, 2016, the coverage of which is at issue here—was “covered by Medicare.” Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court’s review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court’s review in this case, and no response is required.

72. This paragraph consists of plaintiff’s legal conclusions and characterizations of the proceedings in ALJ Appeal No. 1-6020086584R1. No response to the legal conclusions is required, and the characterizations are denied. It is specifically denied that, in ALJ Appeal No. 1-6020086584R1, ALJ Lambert made any “determinations” regarding “Mrs. Smith’s CGM”—that is, the device she was provided on December 13, 2016, the coverage of which is at issue here. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court’s review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings;

Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case, and no response is required.

73. Denied.

74. Admitted. As noted in response to paragraph 73, the Secretary denies that he could have appealed this decision.

75. This paragraph consists of plaintiff's legal conclusions and characterizations of the proceedings in ALJ Appeal No. 1-6020086584R1. No response to the legal conclusions is required, and the characterizations are denied. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case, and no response is required.

76. Admitted that, as reflected in the administrative record, Mrs. Smith submitted a claim for continuous glucose monitor sensors which were provided on May 15, 2018.

77. Admitted that, as reflected in the administrative record, Mrs. Smith's claim was denied on June 8, 2018.

78. Admitted that, as reflected in the administrative record, Mrs. Smith's claim was denied on redetermination on July 10, 2018.

79. Admitted that, as reflected in the administrative record, Mrs. Smith's claim was denied on reconsideration on August 3, 2018.

80. Admitted that, as reflected in the administrative record, Mrs. Smith sought a hearing before an administrative law judge.

81. Admitted that, as reflected in the administrative record, Administrative Law Judge Win held a hearing on December 11, 2018.

82. The Secretary lacks sufficient knowledge or information to form a belief about the truth of these allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case, and no response is required.

83. Admitted.

84. Admitted that, as reflected in the administrative record, ALJ Win denied coverage of the claim at issue in ALJ Appeal No. 1-8048583213 on the grounds that the underlying device was not durable medical equipment.

85. Admitted that, as reflected in the administrative record, Mrs. Smith submitted a claim for continuous glucose monitor sensors which were provided on November 16, 2017.

86. Admitted.

87. Admitted that, as reflected in the administrative record, Mrs. Smith sought a hearing before an administrative law judge.

88. Admitted that, as reflected in the administrative record, Administrative Law Judge Win held a hearing on February 19, 2019.

89. Admitted.

90. Admitted that, as reflected in the administrative record, ALJ Win denied coverage of the claim at issue in ALJ Appeal No. 1-8048536100 on the grounds that the device in question was not durable medical equipment.

91. Admitted.

92. Admitted that the Medicare Appeals Council affirmed the decisions in ALJ Appeals Nos. 1-8048583213 and 1-8048536100 in a single decision issued on February 26, 2021.

93. Denied.

94. This paragraph consists of plaintiff's legal conclusions and characterizations of the proceedings in Medicare Appeals Council case M-19-1973. No response to the legal conclusions is required, and the characterizations are denied. Admitted that the Medicare Appeals Council held that the device in question was not durable medical equipment within the meaning of the Medicare statute and regulations, as interpreted by CMS Ruling 1682-R. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the administrative record, rather than the allegations of the parties in their respective pleadings; Defendant thus respectfully refers the Court to the administrative record for a full and accurate statement of its contents. To the extent that these allegations are not reflected in the administrative record, they are beyond the scope of the Court's review in this case, and no response is required.

95. Denied.

96. Admitted that Mrs. Smith filed this suit on April 5, 2021.

97. In this paragraph, plaintiff repeats the paragraphs set forth above. The Secretary incorporates by reference his answers to all of the preceding paragraphs as if fully set out herein.

98. This paragraph consists of a request for relief, to which no response is required. The Secretary denies that plaintiff is entitled to the requested relief or any relief whatsoever.

99. This paragraph consists of a request for relief, to which no response is required. The Secretary denies that plaintiff is entitled to the requested relief or any relief whatsoever.

100. In this paragraph, plaintiff repeats the paragraphs set forth above. The Secretary incorporates by reference his answers to all of the preceding paragraphs as if fully set out herein.

101. This paragraph consists of a request for relief, to which no response is required. The Secretary denies that plaintiff is entitled to the requested relief or any relief whatsoever.

102. This paragraph consists of a request for relief, to which no response is required. The Secretary denies that plaintiff is entitled to the requested relief or any relief whatsoever.

103. In this paragraph, plaintiff repeats the paragraphs set forth above. The Secretary incorporates by reference his answers to all of the preceding paragraphs as if fully set out herein.

104. This paragraph consists of a request for relief, to which no response is required. The Secretary denies that plaintiff is entitled to the requested relief or any relief whatsoever.

105. This paragraph consists of a request for relief, to which no response is required. The Secretary denies that plaintiff is entitled to the requested relief or any relief whatsoever.

106. In this paragraph, plaintiff repeats the paragraphs set forth above. The Secretary incorporates by reference his answers to all of the preceding paragraphs as if fully set out herein.

107. This paragraph consists of a request for relief, to which no response is required. The Secretary denies that plaintiff is entitled to the requested relief or any relief whatsoever.

108. This paragraph consists of a request for relief, to which no response is required. The Secretary denies that plaintiff is entitled to the requested relief or any relief whatsoever.

The remaining paragraphs of the complaint contain plaintiff's requested relief, to which no response is required. The Secretary denies that plaintiff is entitled to the requested relief or any relief whatsoever.

The Secretary denies any and all allegations of the complaint not expressly admitted herein.

Dated: September 14, 2021

Respectfully submitted,

BRIAN M. BOYNTON  
Acting Assistant Attorney General

MICHELLE BENNETT  
Assistant Director, Federal Programs Branch

/s/ James Bickford  
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